



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION


*** CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION in a CBI APPENDIX ***

MEMORANDUM

SUBJECT: FourStar® MBG containing *Bacillus thuringiensis* subspecies BMP 144 and *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

TO: Shanaz Bacchus, M.S., Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

FROM: Joel V. Gagliardi, Ph.D., Microbial Ecologist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P) 

THROUGH: John L. Kough, Ph.D., Senior Scientist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P) 

ACTION REQUESTED: Review submitted studies for FIFRA section 3 registration of an EP formulated with two registered pesticide manufacturing-use products, BMP 144 Primary Powder and AM61432 Primary Powder.

CONCLUSION: Product Identity and Characterization – **SUPPLEMENTAL but upgradeable**; Waiver Requests for Health Effects Studies (EP) – **ACCEPTABLE** for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation and Primary Dermal irritation. **Not REQUIRED** for Dermal Sensitization; Product Performance **SUPPLEMENTAL but upgradeable**.

DATA REVIEW RECORD:

Active Ingredients: *Bacillus thuringiensis* subspecies BMP 144 and
Bacillus sphaericus 2362, Serotype H5a5b, strain AML614.

Product Names: FourStar MBG.

Company Name: FourStar Microbial Products, LLC.

EPA Reg. No.: 85685-G.

Chemical Numbers: 006520; 119804.

Decision Number: 464522.

DP Barcodes: 402632.

MRID Nos.: 487651-01; 487651-02; 487651-03; 487651-04.

SUMMARY OF REVIEWED DATA:

STUDY TYPES: Product Identity; Manufacturing Process; Discussion of Formation of Unintentional Ingredients; Analysis of Samples; Certification of Limits; Enforcement Analytical Method; Physical and Chemical Characteristics.

OCSPP Guidelines: 885.1100; 885.1200; 885.1300; 885.1400; 885.1500; 830.1800; 830.6302-830.7300.

TEST MATERIAL: FourStar® MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

MRID NO.: 487651-01.

DISCUSSION: Fourstar® MBG is a mixture of two registered pesticides (3% each) with 94% added inert ingredients. Label application rates are similar to those of the registered products currently marketed, including end-use product mixtures also containing both *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

CLASSIFICATION: SUPPLEMENTAL but upgradeable when 1) the CSF and label match those for the active ingredients, 2) culture collection information is provided on the CSF for each active ingredient, 3) a 5-batch analysis addressing storage stability and corrosion characteristics data is submitted to support label claims.

WAIVER REQUESTS: Acute Oral Toxicity; Acute Dermal Toxicity; Acute Inhalation Toxicity; Primary Eye Irritation; Primary Dermal irritation; Dermal Sensitization.

OCSPP Guidelines: 870.1100; 870.1200; 870.1300; 870.2400; 870.2500; 870.2600.

TEST MATERIAL: FourStar® MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

MRID NO.: 487651-02.

DISCUSSION: A formulator's exemption was requested and is appropriate for purposes of assessing the safety of the mixed active ingredients, *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614. Since the formulation under review is an end-use product, only additive effects of the inert ingredients need be considered, and an OCSPP 870.2600 Dermal Sensitization study is not required. Non water inert ingredients in decreasing quantity order are exempt from a tolerance requirement under 40 CFR 180.910 (pre- and post-harvest), 180.960 (polymer), 180.950e (minimal risk), 180.950a (commonly consumed food), and to a lesser extent small amounts of ingredients exempt under 180.920 (pre-harvest) and 180.930 (application to animals). There are two use patterns, commercial and residential, and two basic formulations, a coated granule and a water-soluble pouch. None of the application scenarios, coupled with label cautions and use patterns, engender concerns for additional safety precautions regarding formulation inert ingredients to skin, through inhalation, through ingestion or to the eye.

CLASSIFICATION: ACCEPTABLE for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation and Primary Dermal irritation. **Not REQUIRED** for Dermal Sensitization.

STUDY TYPE: Invertebrate Control Agent Product Performance Test Guidelines - Mosquito, black fly and biting midge (sand fly) treatments.

OCSPP Guideline: 810.3400.

TEST MATERIAL: FourStar® MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

MRID No.: 487651-03.

DISCUSSION: Microcosms were used to simulate field water conditions for exposure of Fourstar® MBG to two species of *Culex* mosquito larvae. At 5 lbs. per acre, efficacy was demonstrated to 43 days with mortality of at least 95%, while at 7.5 lbs. per acre sampling lasted to 43 days still showing 100% mortality of *Culex quinquefasciatus* and *Culex stigmatosoma* mosquitoes. Maintenance of water temperature while air temperature fluctuates is indicative of larger water bodies treated with Fourstar® MBG. However, lighting of the outdoor microcosms was not mentioned and it is assumed they were shaded from direct sunlight.

CLASSIFICATION: SUPPLEMENTAL but upgradeable when lighting conditions to microcosms are described.

STUDY TYPE: Invertebrate Control Agent Product Performance Test Guidelines - Mosquito, black fly and biting midge (sand fly) treatments.

OCSPP Guideline: 810.3400.

TEST MATERIAL: FourStar® MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

MRID No.: 487651-04.

DISCUSSION: Microcosms were used to simulate field water catch basins for exposure of Fourstar® MBG to two species of *Culex* mosquito larvae. With one 10g pouch added per microcosm, efficacy was demonstrated to 66 days showing 98.9% mortality of *Culex quinquefasciatus* and to 74 days showing 93% mortality of *Culex stigmatosoma* mosquitoes. Maintenance of water temperature while air temperature fluctuates is indicative of larger water bodies treated with Fourstar® MBG. However, lighting of the outdoor microcosms was not mentioned and it is assumed they were shaded from direct sunlight. The label specifies use of one pouch per 50 ft.² of water however there is no way to compare study results since the label does not specify the dose provided per pouch.

CLASSIFICATION: SUPPLEMENTAL but upgradeable when the label is updated to show contents of each water soluble pouch, and lighting conditions to simulated catch basins are described.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D. *JVG*

Secondary Review by: John L. Kough, Ph.D.

Study Types	Product Identity (OCSPP 885.1100); Manufacturing Process (885.1200); Discussion of Formation of Unintentional Ingredients (885.1300); Analysis of Samples (885.1400); Certification of Limits (885.1500); Enforcement Analytical Method (830.1800); Physical and Chemical Characteristics (830.6302 - 830.7300).
MRID No.	487651-01.
Test Material	FourStar® MBG containing 3% <i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> BMP 144 and 3% <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain AML614.
Study No.	None given.
Sponsor	FourStar Microbial Products, LLC; 3330 Noyac Road, Building. E; Sag Harbor, NY 11963.
Testing Facility	FourStar Microbial Products, LLC; 3330 Noyac Road, Building. E; Sag Harbor, NY 11963.
Title of Report	Product Chemistry for FourStar® MBG.
Author	Robert D. Sjogren, Ph.D.
Study Completed	March 12, 2012.
Study Summary	Fourstar® MBG is a mixture of two registered pesticides (3% each) with 94% added inert ingredients. Label application rates are similar to those of the registered products currently marketed, including end-use product mixtures also containing both <i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> BMP 144 and <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain AML614.
Classification	SUPPLEMENTAL but upgradeable – when 1) the CSF and label match those for the active ingredients, 2) culture collection information is provided on the CSF for each active ingredient, 3) a 5-batch analysis addressing storage stability and corrosion characteristics data is submitted to support label claims.
Good Laboratory Practice	Signed and dated GLP statements were included; studies were not conducted in accordance with the requirements of 40 CFR Part 160; no study director was assigned and no quality assurance unit was in place.

Test Material: FourStar® MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 - EPA Reg. No. 62637-7, and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614 - EPA Reg. No. 84268-1.

I. PRODUCT IDENTITY:

3% of EPA Reg. No. 62637-7; BMP 144 Primary Powder / Aquabac® Primary Powder containing 100% *Bacillus thuringiensis* subspecies *israelensis* BMP 144; 7,040 International Toxic Units per mg. Disposition of this strain in the Institut Pasteur culture collection as IPS-82 was verified online; this information should also appear on the FourStar® MBG CSF as it does on the BMP 144 Primary powder CSF. The CAS No. 68038-71-1 does not apply and is not consistent with the original label and CSF.

3% of EPA Reg. No. 84268-1; AM61432 Primary Powder / Spheratax Primary Powder containing 100% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614; 1,000 International Toxic Units per mg. This product is incorrectly identified in this volume and on the CSF; the CAS # 143447-72-7 does not apply and the a.i. is not listed according to the original label and CSF. Additionally, culture collection deposit of this strain has not been verified and is not listed on the CSF. Previous references to ATCC 1170 could not be confirmed as this is not currently in the ATCC collection and was not a *Bacillus* species when it was. According to the ATCC listing of the type strain for *Bacillus sphaericus* (ATCC 14577) this organism was subsequently re-classified as *Lysinibacillus sphaericus*.

94% inert ingredients (see appendix).

References:

Ahmed, I., A. Yokota, A. Yamazoe, and T. Fujiwara. 2007. Proposal of *Lysinibacillus boronitolerans* gen. nov. sp. nov., and transfer of *Bacillus fusiformis* to *Lysinibacillus fusiformis* comb. nov. and *Bacillus sphaericus* to *Lysinibacillus sphaericus* comb. nov. International Journal of Systematics and Evolutionary Microbiology 57(5):1117-1125.

Current End-Use Products Containing These Active Ingredients:Table 1: Registered Products Containing *Bacillus sphaericus*

Reg. #	Registration Name	Company Name	% AI	Max Rate*	Eff. Rate
73049-20	VECTOLEX CG BIOLOGICAL LARVICIDE	VALENT BIOSCIENCES CORPORATION	7.5	20 lbs/acre	15 U lbs/acre
73049-57	VECTOLEX WDG BIOLOGICAL LARVICIDE	VALENT BIOSCIENCES CORPORATION	51.2	1.5 lbs/acre	76.8 U-lbs/acre
73049-429	V60035 CG	VALENT BIOSCIENCES CORPORATION	2.7	20 lbs/acre	54 U-lbs/acre
83362-3	FOURSTAR BRIQUETS	B2E MICROBIALS, LLC	6	Briquet	
84268-2	AM61432 (50 G)	ADVANCED MICROBIOLOGICS, LLC	5	20 lbs/acre	100 U-lbs/acre
84268-3	AM61432 WP	ADVANCED MICROBIOLOGICS, LLC	65	1.5 lbs/acre	97.5 U-lbs/acre
85685-2	FOURSTAR CRG	FOURSTAR MICROBIAL PRODUCTS, LLC	9	20 lbs/acre	180 U-lbs/acre
85685 G	FourStar MBG	FOURSTAR MICROBIAL PRODUCTS, LLC	3	20 lbs/acre	60 U-lbs/acre

* Excluding waste tires.

Table 2: Registered Products Containing *Bacillus thuringiensis* subspecies *israelensis* BMP 144

Reg. #	Registration Name	Company Name	% AI	Max Rate	Eff. Rate
432-1515	BES0531	BAYER ENVIRONMENTAL SCIENCE	10	2 lbs/acre	20 U-lbs/acre
769-992	ALLPRO SUSTAIN BCG	VALUE GARDENS SUPPLY, LLC	5.71	8 lbs/acre	45.68 lbs/acre
6218-47	SUMMIT B.T.I. BRIQUETS	SUMMIT CHEMICAL CO	10.31	Briquet	
62637-1	BMP 144 (2X)	BECKER MICROBIAL PRODUCTS, INC	8	8 lbs/acre	64 U-lbs/acre
62637-2	BMP 144 (3X)	BECKER MICROBIAL PRODUCTS, INC	12	1 lbs/acre	12 U lbs/acre
62637-3	BMP 144 (200 G)	BECKER MICROBIAL PRODUCTS, INC	2.86	10 lbs/acre	28.6 U-lbs/acre
62637-11	BMP 144 DF	BECKER MICROBIAL PRODUCTS, INC	17.15	2 lbs/acre	34.3 U-lbs/acre
62637-12	BMP 144 DFX	BECKER MICROBIAL PRODUCTS, INC	25.7	1.3 lbs/acre	33.4 U-lbs/acre
62637-13	BMP 144 (400 G)	BECKER MICROBIAL PRODUCTS, INC	5.71	8 lbs/acre	45.7 U-lbs/acre
62637-14	BMP 144DF 3000	BECKER MICROBIAL PRODUCTS, INC	43	3.5 lbs/acre	150.5 U-lbs/acre
83362 1	LarvXSG	B2E MICROBIALS, LLC	0.26	20 lbs/acre	5.2 U lbs/acre
83362-2	MERIDIAN-02	B2E MICROBIALS, LLC	7	Briquet	
83362-3	FOURSTAR BRIQUETS	B2E MICROBIALS, LLC	1	Briquet	
85685-1	FOURSTAR SBG	FOURSTAR MICROBIAL PRODUCTS, LLC	2.15	10 lbs/acre	21.5 U-lbs/acre
85685-2	FOURSTAR CRG	FOURSTAR MICROBIAL PRODUCTS, LLC	1	20 lbs/acre	20 U-lbs/acre
85685-G	FourStar MBG	FOURSTAR MICROBIAL PRODUCTS, LLC	3	20 lbs/acre	60 U-lbs/acre

Deficiencies: None.

II. MANUFACTURING PROCESS: MSDSs were provided for all inert ingredients. Labels and CSFs for the two registered active ingredients are on hand.

Deficiencies: None.

III. DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS: see appendix.

Deficiencies: None.

IV. ANALYSIS OF SAMPLES: Production has not begun so for this portion there is no data to submit.

Deficiencies: A minimum 5-production batch analysis is required.

V. ENFORCEMENT ANALYTICAL METHOD: The reviewer is directed to the methods on file for the registered product used to formulate FourStar[®] MBG.

Deficiencies: None.

VI. CERTIFICATION OF LIMITS: see appendix.

VII. PHYSICAL AND CHEMICAL CHARACTERISTICS: See Table 3.

Deficiencies: Storage stability and corrosion characteristics studies were not submitted.

TABLE 3. Physical and Chemical Properties for FourStar [®] MBG containing <i>B. thuringiensis</i> subsp. <i>israelensis</i> BMP 144 and <i>B. sphaericus</i> 2362, Stp. H5a5b, str. AML614 ^a		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Not applicable, the product is not a TGA1.	
830.6303 Physical State	Solid granule.	Visual inspection at room temperature.
830.6304 Odor	Not applicable, the product is not a TGA1.	
830.6313 Stability	Not applicable, the product is not a TGA1.	
830.6317 Storage Stability	Study ongoing, expected in Q1 2013.	Visual inspection over 1 year.
830.6319 Miscibility	Not applicable, the product is not an emulsifiable liquid.	
830.6320 Corrosion Characteristics	Study ongoing, expected in Q1 2013.	Visual inspection over 1 year.
830.7000 pH	Not applicable, the product is not a TGA1.	
830.7100 Viscosity	Not applicable, the product is not a liquid.	
830.7300 Density/Relative Density/Bulk Density	1.05 g/cm ³	Hydrostatic displacement.

^aData from page 9 of 68 MRID 487651-01.

FIFRA CBI APPENDIX

Manufacturing process information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

DATA EVALUATION RECORDReview by: Joel V. Gagliardi, Ph.D. 

Secondary Review by: John L. Kough, Ph.D.

Study Types	Waiver requests for: Acute Oral Toxicity (OCSPP 870.1100); Acute Dermal Toxicity (OCSPP 870.1200); Acute Inhalation Toxicity (OCSPP 870.1300); Primary Eye Irritation (OCSPP 870.2400); Primary Dermal irritation (OCSPP 870.2500); Dermal Sensitization (OCSPP 870.2600).
MRID Nos.	487651-02.
Test Material	FourStar [®] MBG containing 3% <i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> BMP 144 and 3% <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain AML614.
Study No.	None given.
Sponsor	FourStar Microbial Products, LLC; 3330 Noyac Road, Building. E; Sag Harbor, NY 11963.
Testing Facility	FourStar Microbial Products, LLC; 3330 Noyac Road, Building. E; Sag Harbor, NY 11963.
Titles of Reports	Response to Tier 1 Microbial Pesticide Data Requirements for FourStar [®] MBG.
Author	Beth E. Milesen, Ph.D., DABT.
Studies Completed	March 13, 2012.
Study Summary	A formulator's exemption was requested and is appropriate for purposes of assessing the safety of the mixed active ingredients, <i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> BMP 144 and <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain AML614. Since the formulation under review is an end-use product, only additive effects of the inert ingredients need be considered, and an OCSPP 870.2600 Dermal Sensitization study is not required. Non water inert ingredients in decreasing quantity order are exempt from a tolerance requirement under 40 CFR 180.910 (pre- and post-harvest), 180.960 (polymer), 180.950e (minimal risk), 180.950a (commonly consumed food), and to a lesser extent small amounts of ingredients exempt under 180.920 (pre-harvest) and 180.930 (application to animals). There are two use patterns, commercial and residential, and two basic formulations, a coated granule and a water-soluble pouch. None of the application scenarios, coupled with label cautions and use patterns, engender concerns for additional safety precautions regarding formulation inert ingredients to skin, through inhalation, through ingestion or to the eye.
Classification	ACCEPTABLE for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation and Primary Dermal irritation. Not REQUIRED for Dermal Sensitization.
Good Laboratory Practice	Study does not meet the requirements for 40 CFR Part 160 – waiver request, not a scientific study.

DISCUSSION: The registrant is requesting data waivers for all health effects data requirements, plus Dermal Sensitization effects for this mixture of two active ingredients each at 3%, with unique inerts. Since a formulator's exemption was requested and is appropriate for purposes of assessing the safety of the mixed active ingredients, this portion of the risk assessment is deferred to previous assessments of the active ingredients *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614. Since the formulation under review is an end-use product, according to the data requirement footnotes at 40 CFR 158.2140 only additive effects of the inert ingredients need be considered, and an OCSPP 870.2600 Dermal Sensitization study is not required.

JUSTIFICATION:

Non water inert ingredients in decreasing quantity order are exempt from an FFDCA tolerance requirement under 40 CFR 180.910 (pre- and post-harvest), 180.960 (polymer), 180.950e (minimal risk), 180.950a (commonly consumed food), and to a lesser extent small amounts of ingredients exempt under 180.920 (pre-harvest) and 180.930 (application to animals). There are two use patterns, commercial and residential, and two basic formulations, a coated granule and a water-soluble pouch. None of the application scenarios, coupled with label cautions and use patterns, engender concerns for additional safety precautions regarding formulation inert ingredients to skin, through inhalation, through ingestion or to the eye.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D.

Secondary Review by: John L. Kough, Ph.D.

Study Types	Invertebrate Control Agent Product Performance Test Guidelines - Mosquito, black fly and biting midge (sand fly) treatments (OCSPP 810.3400).
MRID Nos.	487651-03.
Test Material	FourStar® MBG containing 3% <i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> BMP 144 and 3% <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain AML614.
Study No.	112411.
Sponsor	FourStar Microbial Products, LLC; 3330 Noyac Road, Building. E; Sag Harbor, NY 11963.
Testing Facilities	Consulting Medical Entomologist; 7237 Boice Lane; Riverside, CA 92506.
Titles of Reports	Field Evaluation of FourStar® MBG against <i>Culex quinquefasciatus</i> and <i>Culex stigmatosoma</i> in Microcosms.
Author	Tianyun Su, Ph.D.
Studies Completed	November 24, 2011.
Study Summaries	Microcosms were used to simulate field water conditions for exposure of Fourstar® MBG to two species of <i>Culex</i> mosquito larvae. At 5 lbs. per acre, efficacy was demonstrated to 43 days with mortality of at least 95%, while at 7.5 lbs. per acre sampling lasted to 43 days still showing 100% mortality of <i>Culex quinquefasciatus</i> and <i>Culex stigmatosoma</i> mosquitoes. Maintenance of water temperature while air temperature fluctuates is indicative of larger water bodies treated with Fourstar® MBG. However, lighting of the outdoor microcosms was not mentioned and it is assumed they were shaded from direct sunlight.
Classification	SUPPLEMENTAL but upgradeable – when lighting conditions to microcosms are described.
Good Laboratory Practice	Studies meet 40 CFR 160 with exceptions: there is no QA audit, the stability and characterization of the test substance was the responsibility of the study sponsor, signatures of individual research assistants were not obtained, and the study sponsor will archive all signed reports and protocols.

TEST SUBSTANCE: FourStar® MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614.

MATERIALS AND METHODS:

Test Material: Fourstar® MBG granules at 5 or 7.5 lbs. per acre, 217 or 326 mg/tub.

Habitat: Simulated field, outdoor microcosms with 4.17 ft² water surface area in 20" tall containers containing 10.5 gallons of water; 4 replicates of each treatment and control. Later in the methods section maintenance of a depth of 6" and volume of 12.5 gallons is listed, though this variation is not expected to significantly alter the reported results.

Mosquitoes: *Culex quinquefasciatus* Say late 2nd instar

Culex stigmatosoma Dyar late 2nd instar

Mosquitoes (25 ea.) were confined to floating cages to demonstrate efficacy of granules that sink.

Feed: Alfalfa pellets at 0.0125% per tub.

Efficacy Evaluation: Mosquito larvae mortality was recorded at pupation, cohort mosquitoes were removed and additional mosquitoes were added to the test microcosms until cohort mortality declined below 95%. Pupations for cohorts were recorded at: 7 days, 15 days, 22 days, 29 days, 35 days, and 43 days.

RESULTS:

Mortality: *Culex quinquefasciatus* and *Culex stigmatosoma*

5 lbs./acre: average of 98.3% mortality over 43 days

95% mortality at day 43 for *Culex quinquefasciatus*

97% mortality at day 35 for *Culex stigmatosoma*.

7.5 lbs./acre: average of 100% mortality over 43 days

100% mortality at day 43 for *Culex quinquefasciatus*

100% mortality at day 35 for *Culex stigmatosoma*.

Untreated: 4.0-7.0% (4.8% average)

Air and Water Temperature:


Water: 83-85°F maintained by a submerged heater set to 85°F.

Air: 36-52°F minimums to 68-81°F maximums.

DISCUSSION:

Maintenance of water temperature while air temperature fluctuates is indicative of larger water bodies treated with Fourstar® MBG. However, lighting of the outdoor microcosms was not mentioned and it is currently assumed they were shaded from direct sunlight.

DATA EVALUATION RECORD

Review by: Joel V. Gagliardi, Ph.D. 

Secondary Review by: John L. Kough, Ph.D.

Study Types	Invertebrate Control Agent Product Performance Test Guidelines - Mosquito, black fly and biting midge (sand fly) treatments (OCSPP 810.3400).
MRID Nos.	487651-04.
Test Material	FourStar [®] MBG containing 3% <i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> BMP 144 and 3% <i>Bacillus sphaericus</i> 2362, Serotype H5a5b, strain AML614.
Study Nos.	100911b.
Sponsor	FourStar Microbial Products, LLC; 3330 Noyac Road, Building. E; Sag Harbor, NY 11963.
Testing Facilities	Consulting Medical Entomologist; 7237 Boice Lane; Riverside, CA 92506.
Titles of Reports	Field Evaluation of FourStar [®] MBG Water Soluble Pouch against <i>Culex quinquefasciatus</i> and <i>Culex stigmatosoma</i> in Simulated Catch Basin Microcosms.
Author	Tianyun Su, Ph.D.
Studies Completed	December 22, 2011.
Study Summaries	Microcosms were used to simulate field water catch basins for exposure of Fourstar [®] MBG to two species of <i>Culex</i> mosquito larvae. With one 10g pouch added per microcosm, efficacy was demonstrated to 66 days showing 98.9% mortality of <i>Culex quinquefasciatus</i> and to 74 days showing 93% mortality of <i>Culex stigmatosoma</i> mosquitoes. Maintenance of water temperature while air temperature fluctuates is indicative of larger water bodies treated with Fourstar [®] MBG. However, lighting of the outdoor microcosms was not mentioned and it is assumed they were shaded from direct sunlight. The label specifies use of one pouch per 50 ft. ² of water however there is no way to compare study results since the label does not specify the dose provided per pouch.
Classification	SUPPLEMENTAL but upgradeable – when the label is updated to show contents of each water soluble pouch, and lighting conditions to simulated catch basins are described.
Good Laboratory Practice	Studies meet 40CFR160 with exceptions: there is no QA audit, the stability and characterization of the test substance was the responsibility of the study sponsor, signatures of individual research assistants were not obtained, and the study sponsor will archive all signed reports and protocols.

TEST SUBSTANCE: FourStar[®] MBG containing 3% *Bacillus thuringiensis* subspecies *israelensis* BMP 144 and 3% *Bacillus sphaericus* 2362, Serotype H5a5b, strain AML614; 10g granules in a water soluble pouch.

MATERIALS AND METHODS:

Habitat: Plastic tubs 28" tall with a 4 ft² surface area filled with 35 gallons water and 4" top soil, fermented 14 days after flooding and addition of feed, four replicates each for treated and control. Simulated catch basins were flushed weekly and 10% of the water volume was exchanged. Each simulated catch basin received 10g Fourstar[®] MBG in a single pouch.

Mosquitoes: *Culex quinquefasciatus* Say late 2nd instar

Culex stigmatosoma Dyar late 2nd instar

Mosquitoes (25 ea.) were confined to floating cages to demonstrate efficacy of granules that sink.

Feed: Alfalfa pellets (100g/tub).

Efficacy Evaluation: Mosquito larvae mortality was recorded at pupation, cohort mosquitoes were removed and additional mosquitoes were added to the test microcosms until cohort mortality declined below 93%. Pupations for cohorts were recorded at: 10 days, 17 days, 24 days, 31 days, 38 days, 45 days, 53 days, 59 days, 66 days, and 74 days.

RESULTS:

Mortality: *Culex quinquefasciatus* and *Culex stigmatosoma*

1 Pouch: average of 98.6% mortality over 74 days

98.6% mortality at day 66 for *Culex quinquefasciatus*

93% mortality at day 74 for *Culex stigmatosoma*.

Untreated: 3.0-7.0% (5.1% average)

Air and Water Temperature:

Water: 65-73°F minimum to 67-82°F maximum, maintained by a submerged heater set to 70°F.

Air: 34.9-56.1°F minimums to 80-91°F maximums.

DISCUSSION:

Maintenance of water temperature while air temperature fluctuates is indicative of larger water bodies treated with Fourstar® MBG. However, lighting of the outdoor microcosms was not mentioned and it is currently assumed they were shaded from direct sunlight.